In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 19-1570V
Filed: July 11, 2023
PUBLISHED

VANESSA MORRIS,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Maximillian J. Muller, Muller Brazil, LLP, Dresher, PA, for petitioner.
Benjamin Patrick Warder, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

On October 9, 2019, petitioner, Vanessa Morris, filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012),[2] alleging that she suffered a "Shoulder Injury Related to Vaccine Administration" or "SIRVA" following an influenza ("flu") vaccination she received on October 4, 2017. (ECF No. 1.) For the reasons set forth below, I conclude that petitioner is entitled to compensation.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute;

[1] Because this document contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. *See* 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the document will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information the disclosure of which would constitute an unwarranted invasion of privacy. If the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

[2] Within this decision, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a causal link between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

As relevant here, the Vaccine Injury Table lists a Shoulder Injury Related to Vaccine Administration or "SIRVA" as a compensable injury if it occurs within 48 hours of vaccine administration. § 300aa-14(a) as amended by 42 CFR § 100.3. Table Injury cases are guided by statutory "Qualifications and aids in interpretation" ("QAIs"), which provide more detailed explanation of what should be considered when determining whether a petitioner has actually suffered an injury listed on the Vaccine Injury Table. 42 CFR § 100.3(c). To be considered a "Table SIRVA," petitioner must show that her injury fits within the following definition:

> SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis . . . . A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time-frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 CFR § 100.3(c)(10).

Alternatively, if no injury falling within the Table can be shown, the petitioner may still demonstrate entitlement to an award by showing that the vaccine recipient's injury was caused-in-fact by the vaccination in question. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(ii). To so demonstrate, a petitioner must show that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). In particular, a petitioner must show by preponderant evidence: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury in order to prove causation-in-fact. *Althen v. Sec'y of Health & Human Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005).

For both Table and Non–Table claims, Vaccine Program petitioners must establish their claim by a "preponderance of the evidence". § 300aa-13(a). That is, a petitioner must present evidence sufficient to show "that the existence of a fact is more probable than its nonexistence . . . ." *Moberly*, 592 F.3d at 1326 n.2. Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). However, a petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1). Once a petitioner has established their *prima facie* case, the burden then shifts to respondent to prove, also by preponderant evidence, that the alleged injury was caused by a factor unrelated to vaccination. *Althen,* 418 F.3d at 1278 (citations omitted); § 300aa-13(a)(1)(B).

II. Procedural History

Petitioner filed medical records marked as Exhibits 1-10 and an affidavit marked as Exhibit 11 at the time she filed her petition. (ECF No 1.) The case was initially assigned to the Special Processing Unit ("SPU") based on the allegations of the petition. (ECF No. 8.) Additional medical records and affidavits marked as Exhibits 12-14 were filed in January and February of 2020. (ECF Nos. 11-13.) The parties attempted settlement, but reached an impasse as of May of 2021. (ECF No. 23.)

Respondent filed his Rule 4 Report on August 24, 2021. (ECF No. 26.) Respondent primarily raised the issue that petitioner had not established onset of her condition within 48 hours of vaccination as required for a Table SIRVA. (*Id*. at 13-14.) Respondent additionally observed that no expert report had been filed to support any cause in fact claim as of the time of filing. (*Id*. at 14.)

On December 15, 2021, the Chief Special Master issued a finding of fact. (ECF No. 30; *see also Morris v. Sec'y of Health & Human Servs*., No. 19-1570V, 2021 WL 6504390 (Fed. Cl. Spec. Mstr. Dec. 15, 2021).) The Chief Special Master concluded

that onset of petitioner's shoulder pain was outside of 48 hours, but within 72 hours, of her vaccination. (*Id*. at 8.) Accordingly, he dismissed petitioner's Table claim and urged the parties to explore informal resolution of the remaining off-Table claim. (*Id*.)

As of January 14, 2022, the parties again reported they were unable to resolve the case. (ECF No. 31.) It was then reassigned to the undersigned on January 19, 2022. (ECF No. 34.) Thereafter, petitioner filed an expert report by Naveed Natanzi, DO, on February 17, 2022. (ECF No. 35; Exs. 15-37.) Petitioner filed a further report by Eric Gershwin, M.D., on May 9, 2022. (ECF No. 38; Exs. 38-43.)

I allowed respondent an opportunity to file a responsive expert report; however, on June 10, 2022, respondent indicated that he did not believe filing a responsive expert report would be productive and instead requested that the case by resolved based on the existing record. (ECF No. 39.) Petitioner filed a motion for a ruling on the written record on August 23, 2022. (ECF No. 41.) Respondent filed his response on November 4, 2022. (ECF No. 43.) Petitioner did not file any reply.

In light of the above I have determined that the parties have had a full and fair opportunity to present their cases and that it is appropriate to resolve this issue without a hearing. *See* Vaccine Rule 8(d); Vaccine Rule 3(b)(2); *Kreizenbeck v. Sec'y of Health & Human Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020) (noting that "special masters must determine that the record is comprehensive and fully developed before ruling on the record"). Accordingly, this matter is now ripe for resolution.

III. Factual History

Petitioner received the flu vaccine at issue in this case in her left arm on October 4, 2017. (Ex. 1.) Respondent agrees that she had no prior history of left shoulder problems. (ECF No. 43, p. 4 (citing Ex. 2, pp. 22-23, 25-26, 161-199; Ex. 7, pp. 3-9; Ex. 9, pp. 7-62; Ex. 10, pp .7-78).) Because the question of onset has already been resolved in a separate published ruling, this fact summary does not repeat all of the medical record entries that were discussed in the prior finding of fact with respect to onset. For a more detailed discussion of onset, *see Morris*, *supra*, at 2021 WL 6504390. Per that fact finding, petitioner began experiencing left shoulder pain between 48 to 72 hours after her vaccination.

On November 8, 2017, petitioner called her primary care provider reporting pain in her left arm since receiving the flu vaccination. (Ex. 2, p. 20.) She reported being unable to move her arm. (*Id*.) Petitioner subsequently presented to Dr. Ragahavan on November 15, 2017. (*Id.* at 18-19.) Dr. Ragahaven's physical exam confirmed limited range of motion due to pain, but no weakness. Dr. Ragahaven assessed "left arm pain" attributed to a "vaccine reaction" and referred petitioner to physical therapy. (*Id*. at 18-19.) Petitioner's physical therapy evaluation further confirmed her restricted range of motion. (Ex. 3, pp. 153-55.) She was discharged from physical therapy on January 14, 2018, with minimal improvement. (*Id*. at 180-81.)

Petitioner returned to Dr. Ragahaven on January 24, 2018, reporting that physical therapy had worsened her pain. (Ex. 2, pp. 16-17.) An ultrasound was negative for any mass or fluid collection and the radiologist recommended an MRI to evaluate for Parsonage-Turner Syndrome. (Ex. 8, p. 139.) Dr. Ragahaven referred petitioner to a neurologist on January 25, 2018. (Ex. 2, p. 15.)

Petitioner presented to neurologist Julia McCoy, M.D. on February 6, 2018. (Ex. 2, pp. 155-60.) Petitioner denied numbness, tingling, or radiating symptoms. (*Id.* at 155.) She did have decreased range of motion. (*Id*.) Dr. McCoy diagnosed "influenza injection induced adhesive capsulitis" and not Parsonage-Turner Syndrome. (*Id*. at 157.) She referred petitioner to an orthopedist. (*Id*.)

Petitioner then presented to orthopedist Martin Siems, M.D., on February 22, 2018. (Ex. 5, pp. 26-27.) X-ray imaging showed mild acromioclavicular joint arthrosis and a small inferior head spur. (*Id*. at 26.) Dr. Siems diagnosed adhesive capsulitis and a possible rotator cuff tear. (*Id.*) An MRI was ordered to rule out a rotator cuff tear. (*Id.*) A left shoulder MRI of February 28, 2018, showed mild acromioclavicular joint arthritis, subacromial bursitis, and mild thickening of the inferior joint capsule suggestive of adhesive capsulitis. (*Id*. at 57-58.) Dr. Siems performed a left shoulder manipulation under general anesthesia on March 12, 2018. (Ex. 6, p.5) The postoperative diagnosis was adhesive capsulitis. (*Id*. at 5.)

Petitioner continued to be symptomatic and continued to seek treatment. On July 3, 2018, petitioner had a surgical consultation with Jonathan Wyatt, M.D. (Ex. 5, pp. 15-17.) He diagnosed adhesive capsulitis, biceps tendonitis, and impingement. (*Id*. at 16.) On August 9, 2018, Dr. Wyatt performed an arthroscopic capsular release, biceps tenotomy, subacromial decompression, and manipulation under anesthesia. (*Id*. at 39-41.) The postoperative diagnoses were adhesive capsulitis, biceps tendinitis, and impingement. (*Id*. at 39.) Although this did not resolve petitioner's symptoms, the underlying nature of petitioner's condition was not revisited in any of her subsequent treatment records.

IV. Expert Reports

a. Dr. Natanzi

Dr. Natanzi opines that inadvertent overpenetration of a vaccine needle into the subacromial bursa can result in an exaggerated immune response that in turn leads to inflammation of the structures of the shoulder joint, resulting in, *inter alia*, bursitis and adhesive capsulitis. (Ex. 15, pp. 8-9.) These types of post-vaccination injuries have been collected into the phenomenon known as "Shoulder Injury Related to Vaccine Administration" or "SIRVA," which he acknowledges does not constitute a medical diagnosis in itself. (*Id*. at 7.) Based on his own review of the medical records, Dr. Natanzi opines that petitioner experienced onset of shoulder pain within 48 hours of her vaccination; however, he stresses no two patients are exactly alike and that the 48-hour period represents merely a "typical" timeframe. Thus, given the finding of a 72-hour

onset in this case, he confirms that in his opinion an onset of 72 hours should not preclude attributing a shoulder injury to vaccination. (*Id*. at 7-8.) Dr. Natanzi opines that petitioner's own specific diagnosis of adhesive capsulitis is consistent with SIRVA literature and that her MRI finding of bursitis is a further hallmark of the pathologic process believed to be involved in SIRVA. (*Id*. at 8.) He concludes that "[g]iven the outlined temporal relationship of symptoms to the vaccine, the subjective and objective signs of a SIRVA, and the absence of any pre-vaccination shoulder dysfunction, it is more likely than not that the influenza vaccination on 10/4/17 caused Ms. Morris' left shoulder dysfunction." (*Id*. at 9.)

b. Dr. Gershwin

Dr. Gershwin endorses Dr. Natanzi's analysis. (Ex. 38, p. 4.) He further asserts that based on his review of literature "[t]he development of symptoms from inflammation are obviously individually determined and the literature supports onset within days, not carved in a concrete 48-hour window." (*Id.* at 3.) Dr. Gershwin explains that, although its etiology is still considered unknown, it is generally accepted that adhesive capsulitis is a progressive condition in which inflammation is believed to eventually lead to fibrosis, resulting in a clinical presentation of pain and reduced range of motion of the shoulder. (*Id*. at 3-4.) He explains that a prior rat study showed that adhesive capsulitis can develop in as little as five days. (*Id*. at 3.) Dr. Gershwin opines that petitioner's own history, including her lack of prior shoulder dysfunction, symptom onset within five days of vaccination, MRI evidence including bursal fluid, and ultimate diagnosis of adhesive capsulitis, all support the conclusion that petitioner suffered vaccine-caused adhesive capsulitis. (*Id*. at 5.)

V. Party Contentions

a. Petitioner's Motion

Petitioner asserts that she has preponderantly satisfied the *Althen* test for causation-in-fact based on her medical history and the opinions of her two experts. (ECF No. 41.) She asserts that her two experts have presented a medical theory under *Althen* prong one demonstrating that adhesive capsulitis is an inflammatory condition that can be caused by vaccination. (*Id*. at pp. 10-12.) Regarding *Althen* prong two, petitioner notes that her primary care physician, Dr. Ragahaven, diagnosed petitioner as having had an adverse vaccine reaction and her treating neurologist, Dr. McCoy, opined petitioner's adhesive capsulitis was due to her vaccination. (*Id*. at p. 12 (citing Ex. 2, pp. 18-19, 157).) Regarding *Althen* prong three, petitioner asserts that 48 hours is when post-vaccination shoulder injuries "commonly" occur and is "not an absolute." (*Id*. at 14.) Petitioner lists several citations she asserts show some patients reported SIRVA at 3 or 4 days post vaccination. (*Id*. (citing Ex. 18, p. 2; Ex. 31, p. 1; Ex. 32, p. 2; Ex. 33, p. 2; Ex. 34, p. 2).) Petitioner stresses that respondent has not come forward with any evidence to suggest that it is unreasonable for her experts to opine that vaccine causation at 72 hours post-vaccination is appropriate. (*Id*. at 16.)

b. Respondent's Response

Respondent's motion response focuses exclusively on whether petitioner has established a medically reasonable temporal relationship between her vaccination and onset of adhesive capsulitis. (ECF No. 43.) Respondent asserts that petitioner's experts provided inconsistent opinions on this point, leaving petitioner unable to meet her burden of proof. (*Id*. at 15-16.) Whereas Dr. Natanzi opined that petitioner's symptoms began "well within 48 hours," consistent with respondent's regulatory rulemaking, Dr. Gershwin opined that onset within five days is appropriate. (*Id*. at 14-15.) Respondent is further critical of Dr. Gershwin's opinion because, according to respondent, the literature he has cited demonstrates a minimum latency of five days for adhesive capsulitis, which is incompatible with the three-day onset in this case. (*Id*. at 16.)

VI. Discussion

a. Table SIRVA

As noted above, the Chief Special Master previously issued a finding of fact determining that onset of petitioner's shoulder pain occurred 72 hours post-vaccination and dismissing petitioner's Table SIRVA claim. (ECF No. 30; 2021 WL 6504390.) The Chief Special Master's ruling is not binding on me. *Godfrey v. Sec'y of Health & Human Servs*., 2015 WL 10710961, at *9 (Fed. Cl. Spec. Mstr. Oct. 27, 2015) (noting that "[g]enerally, special masters may change or revisit any ruling until judgment enters, even if the case has been transferred."); *see also Hanlon v. Sec'y of Health & Human Servs*., 40 Fed. Cl. 625, 630 (1998), *aff'd*, 191 F.3d 1344 (Fed. Cir. 1999) (special masters are not bound by their own or other special masters' decisions). However, upon review of that finding of fact as well as the record as a whole, I agree with the analysis and conclusion of the prior finding of fact and adopt it as my own.

b. Causation-in-Fact

i. *Althen* Prong One

Under *Althen* prong one, petitioner must provide a "reputable medical theory," demonstrating that the vaccine received can cause the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). Such a theory must only be "legally probable, not medically or scientifically certain." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994). Petitioner may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1325-26 (Fed. Cir. 2006)). However, "[a] petitioner must provide a 'reputable medical or scientific explanation' for [her] theory. While it does not require medical or scientific certainty, it must still be 'sound and

reliable.'" *Boatmon v. Sec'y of Health & Human Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019) (quoting *Knudsen*, 35 F.3d at 548-49).

Dr. Natanzi opines that inadvertent overpenetration of a vaccine needle into the subacromial bursa can result in an exaggerated immune response that in turn leads to inflammation of the structures of the shoulder joint, resulting in, *inter alia*, bursitis and adhesive capsulitis. (Ex. 15, pp. 8-9.) Further to this, Dr. Gershwin explains that the pathogenesis of primary adhesive capsulitis likely stems at least in part from an inflammatory reaction that in turn leads to fibrotic changes. (Ex. 38.) Thus, he further endorses Dr. Natanzi's opinion that the post-vaccination inflammatory process can lead to adhesive capsulitis. (*Id*. at 4.) These opinions are supported by various citations to relevant medical literature.

Respondent agrees that adhesive capsulitis is the relevant injury that underlies petitioner's claim. (ECF No. 43, p. 13.) However, he offers no argument refuting petitioner's experts' theory that vaccination can lead to adhesive capsulitis. Nor does he present any competing medical opinion to support such a view. In fact, two key pieces of literature cited by Dr. Natanzi informed respondent's own regulatory rulemaking regarding SIRVA, namely Atanasoff, et al, and Bodor and Montalvo.[3] Proposed Rulemaking, 2015 WL 4538923, at *45136. Special masters have observed with regard to SIRVA that "the very decision to add a claim [to the Vaccine Injury Table] reflects Respondent's determination that valid science supports revising the Table." *E.g.*, *L.J. v. Sec'y of Health & Human Servs*., No. 17-59V, 2021 WL 6845593, at *14 (Fed. Cl. Spec. Mstr. Dec. 2, 2021). Regardless of respondent's argument that the broader SIRVA concept is a creature of his own rulemaking, respondent cannot reasonably argue that these studies which he had already himself specifically endorsed are not persuasive as support for a medical theory of causation. Both Atanasoff and Bodor and Montalvo, support adhesive capsulitis specifically as among the conditions that can be causally related to vaccination. (Atanasoff, *supra*, at Ex. 18, p. 3; Bodor and Montalvo, *supra*, at Ex. 19, p. 2.)

Thus, petitioner has satisfied *Althen* prong one by providing a sound and reliable medical theory demonstrating that a flu vaccination can cause adhesive capsulitis.

ii. *Althen* Prong Three

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

[3] Atanasoff, et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 VACCINE 8094 (2010) (Ex. 18); Bodor and Montalvo, Vaccine related shoulder dysfunction, 25 VACCINE 585 (2007) (Ex. 19).

In stressing Dr. Natanzi's opinion that petitioner suffered onset of shoulder pain within 48 hours of vaccination, respondent mischaracterizes his opinion. Although it is true that Dr. Natanzi assessed an earlier onset himself based on his own review of the records, he additionally addressed the Chief Special Master's prior finding that onset occurred outside of 48 hours of vaccination. In that regard, he explained that

> although SIRVA typically does present within the first couple of days, as alluded to above, no two patients ever present a disease the same. Medical literature supports this, specifically Atanasoff et al., who cited a case where symptom presentation did not present until day four after vaccination. Even if I were to assume the alternative of pain beginning after 48 hours, it would not preclude me from making a SIRVA diagnosis.

(Ex. 15, pp. 6-7.)

I have previously found that the single outlier case from the Atanasoff study is not sufficient standing alone to support petitioner's burden under *Althen* prong three, but I have also found that the overall focus of the body of relevant literature is on what is typical, meaning that the literature does not indicate that onset must fall precisely within 48 hours of vaccination to support causation-in-fact. *Compare Clark v. Sec'y of Health & Human Servs*., No. 18-813V, 2022 WL 16635681 (Fed. Cl. Spec. Mstr. Feb. 7, 2022) *with Murray v. Sec'y of Health & Human Servs.*, No. 17-1357V, 2022 WL 17829797 (Fed. Cl. Spec. Mstr. Oct. 27, 2022); *see also Pitts v. Sec'y of Health & Human Servs.*, No. 18-1512V, 2023 WL 2770943 (Fed. Cl. Spec. Mstr. Apr. 4, 2023).[4] Indeed, the Federal Circuit holding in *Paluck v. Secretary of Health & Human Services* cautions against setting "hard and fast deadline[s]" for onset. *See* 786 F.3d 1373, 1383-84 (Fed. Cir. 2015) (stating that "[t]he special master further erred in setting a hard and fast deadline" for onset and noting that the medical literature filed in the case "do not purport to establish any definitive timeframe for onset of clinical symptoms."). In this case, although he primarily cites to the Atanasoff outlier, Dr. Natanzi's medical opinion with respect to onset is unrebutted by any other medical opinion from any treating physician or expert. It is also further complemented by Dr. Gershwin's additional explanation of the pathogenesis of adhesive capsulitis.

[4] Prior decisions by other special masters have also suggested that onset falling outside of the 48-hour Table window but within less than one week post-vaccination can support a cause-in-fact shoulder injury claim. *Kuczarski v. Sec'y of Health & Human Servs.*, No. 20-0312V, 2023 WL 1777208, at *3-4 (Fed. Cl. Spec. Mstr. Feb. 6, 2023) (dismissing Table SIRVA claim but noting that "a causation-in-fact injury claim might still be tenable, based on an onset occurring a week after vaccination."); *Jewell v. Sec'y of Health & Human Servs.*, No. 16-0670V, 2017 WL 7259139, at * 3 (Fed. Cl. Spec. Mstr. Aug. 4, 2017) (finding entitlement for shoulder injury occurring 72 hours post-vaccination); *but see C.C. v. Sec'y of Health & Human Servs.,* No. 17-708V, 2021 WL 2182817 (Fed. Cl. Spec. Mstr. Mar. 31, 2021) (finding onset of shoulder pain one-week post-vaccination did not satisfy *Althen* prong three because petitioner's *Althen* prong one theory was based on the Vaccine Injury Table, which required a 48-hour onset); *Porcello v. Sec'y of Health & Human Servs.,* No. 17-1255V, 2020 WL 4725507, at *9 (Fed. Cl. Spec. Mstr. June 22, 2020) (denying entitlement where petitioner failed to show onset "reasonably close" in time to vaccination where the only precise notation of onset indicated an 11-day latency).

Dr. Gershwin explains that, while the pathogenesis of adhesive capsulitis is not entirely clear, it likely involves an initial inflammatory process that results in the later development of fibrotic changes. (Ex. 38, pp. 3-4.) Based on a citation to a rat study, he suggests that the development of adhesive capsulitis takes at least five days. (Ex. 38, p. 3,5.) Combining this observation with the other literature regarding SIRVA, which places symptom onset within days of vaccination, he opines that it is medically reasonable for onset of manifestations of post-vaccination adhesive capsulitis to occur as late as five days post vaccination. (*Id*. at 5.) That is, Dr. Gershwin suggests that the fact that the underlying pathogenic process of adhesive capsulitis, inclusive of both inflammation and fibrotic changes, continues over the course of at least five days supports inter-patient variability in the initial outward manifestation of the condition. Thus, he characterizes a specific 48-hour period as "arbitrary." (*Id*. at 2.)

Respondent is critical of Dr. Gershwin's opinion, because the onset of fibrosis in the animal study was *at least* five days, which is not compatible with the earlier onset in this case. However, respondent conflates the onset of symptomology, namely pain, which was found to be 3 days post-vaccination in this case, with the onset of fibrotic changes, as seen in the animals observed to suffer adhesive capsulitis as early as five days post exposure. Because Dr. Gershwin explains adhesive capsulitis to be a progressive condition, this is not necessarily a one-to-one comparison. Although petitioner experienced pain three days post-vaccination, nothing in the medical records is able to confirm whether she had fibrotic changes immediately upon the first manifestations of pain. For example, in one case report cited by Dr. Natanzi, the subject experienced pain within hours of vaccination, but additional signs of adhesive capsulitis developed progressively over a period of six weeks. (Barnes, et al, *A "Needling" Problem: Shoulder Injury Related to Vaccine Administration*, 25 J. OF THE AM. BOARD OF FAM. MED. 6 (Nov.-Dec. 2012) (Ex. 20).) Although adhesive capsulitis is this petitioner's ultimate diagnosis, like the Barnes subject, petitioner's February 28, 2018 MRI also confirmed that she had subacromial bursitis that could have additionally contributed to her overall presentation. (Ex. 5, pp. 24, 57-58.)

Because respondent has opted not to present his own expert opinion, Dr. Natanzi's and Dr. Gershwin's expert medical opinions are unrebutted. I have considered respondent's arguments suggesting that the opinions are facially inadequate, but do not find them persuasive. In particular, I do not agree that Dr. Natanzi's and Dr. Gershwin's opinions are inconsistent. Accordingly, petitioner has satisfied *Althen* prong three.

iii. *Althen* Prong Two

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant*, 956 F.2d at 1148. In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 (quoting *Althen*, 418 F.3d at 1280) (stating

that "medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'"). However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. *See* Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) (stating that "there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). Ultimately, petitioner may support her claim either through her medical records or by expert opinion. § 300aa-13(a)(1).

Here, petitioner's primary care physician initially felt she was suffering arm pain due to a vaccine reaction. (Ex. 2, pp. 18-19.) However, diagnosis remained unclear. In ruling out an alternative diagnosis of Parsonage-Turner Syndrome, petitioner's neurologist specifically opined that petitioner was suffering adhesive capsulitis caused by her vaccine injection and referred petitioner to an orthopedist. (*Id*. at 157.) The orthopedist did not subsequently address the underlying cause of petitioner's condition but did confirm the adhesive capsulitis diagnosis rendered by the neurologist. (Ex. 5, pp. 26-27.) Petitioner has also presented expert medical opinions from two physicians opining that her adhesive capsulitis was caused by her vaccination.

On this record, all of these medical opinions are unrebutted. Moreover, respondent does not raise any issue with respect to preexisting shoulder dysfunction, identify any symptoms beyond the confines of the shoulder, or suggest the presence of any other condition or other trigger that could explain petitioner's adhesive capsulitis. Although these factors overlap with the requirements for a Table SIRVA, they are also considerations relevant to assessing causation-in-fact based on the medical literature that has been filed in this case. Respondent's sole argument that the timing of onset is not medically appropriate is not persuasive for the reasons discussed above.

Thus, petitioner has satisfied *Althen* prong two.

c. Factor Unrelated to Vaccination

After petitioner has met her *prima facie* burden, respondent has the opportunity to identify a factor unrelated to vaccination as the true cause of the condition. § 300aa-13(a)(1)(B). In this case, respondent has not identified any alternative cause for petitioner's condition. Nor has he provided any medical opinion that could preponderantly support such a view.

VII. Conclusion

For all the reasons discussed above, after weighing the evidence of record within the context of this program, I find by preponderant evidence that petitioner suffered a

shoulder injury, specifically adhesive capsulitis, caused-in-fact by her October 4, 2017 flu vaccination. A separate damages order will be issued.

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master